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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,012	06/19/2003	Samuel J. Danishefsky	2003080-0127 (SK-816-CON)	2485
24280	7590	03/04/2004	EXAMINER	
Choate, Hall & Stewart Exchange Place 53 State Street Boston, MA 02109			RUSSEL, JEFFREY, E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,012

Applicant(s)

DANISHEFSKY ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/19/03; 1/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The amino acid sequence Ala-Val-Ala-Val in Figure 18A is subject to the sequence disclosure rules, but is not included in the sequence listing filed June 19, 2003. Further, a SEQ ID NO must be inserted after this sequence in the drawing or more preferably in the Brief Description of Figure 18. See 37 CFR 1.821(d).

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

The Sequence Listing filed June 19, 2003 was approved by STIC for matters of form.

2. This application was filed with a set of 32 sheets of drawings (copies of the drawings originally filed in parent application 09/276,595), a set of 64 sheets of formal drawings, and an amendment to the drawings to which is attached two versions of Figure 9 and two versions of Figure 27. While it seems clear that the set of 64 sheets of formal drawings is supposed to replace the set of 32 sheets of drawings, it is not clear whether the amendment to the drawings is supposed to replace Figures 9 and 27 in the set of 64 sheets of formal drawings, or if the amendment to the drawings relates to the drawings originally filed in the parent application. Neither version of Figure 9 attached to the amendment to the drawings corresponds with Figures 9A, 9B, and 9C of the formal drawings. Note that the former does not separate its structures as

separate figures; that the former includes a variable R' in its upper-most structure; and the former shows four separate chemical structures as opposed to the three chemical structures shown in Figures 9A-9C of the formal drawings. The examiner can not approve any proposed amendments to the drawings until it is clear what the proposed amendments are supposed to be.

3. The preliminary amendment to the specification filed June 19, 2004 is objected to as being in improper format under 37 CFR 1.121(b). Rather than provide a separate marked-up copy of each paragraph of the specification to be amended, Applicants sometimes provide one marked-up copy for several paragraphs of the specification to be amended. See, e.g., page 4, last three lines, and page 7, last two lines, of the preliminary amendment. This has never been a standard amendment format in the Office, and does not satisfy the requirement for an instruction which unambiguously identifies the location to replace a paragraph with one or more replacement paragraphs. Correction is required by re-submission of the entire preliminary amendment to the specification in appropriate form.

The substance of the changes to the specification contained in the preliminary amendment are acceptable.

4. The disclosure is objected to because of the following informalities: The status of parent application 09/276,595 should be updated in the claim for priority at page 1, lines 11-16, of the specification. At page 22, line 18, "glycoconjugate" is misspelled. Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure of the structure recited at claim 59, line 2. In particular, the group $[\text{NH-CH}(\text{CHR}_\text{C}\text{R}_\text{D})\text{-C(O)}]_p$ is not disclosed in the places pointed to by Applicants for support, e.g., at pages 10-11 of the specification, at Figures 25-29, or in claim 1. This group is simply absent from these or any other places in the disclosure. For example, the formula at page 10 of the specification does not permit the diamino group required by the formula of claim 59, and the number of residues permitted by the formula at page 10 ($m+n+p+q \leq 6$) is significantly less than the number of residues permitted by the formula at claim 59 ($n+p=2-12$). While there may be groups in Figures 25-29 which are species of this generic formula, a few species do not provide written descriptive support for this general formula. Originally-filed claim 1 requires at least one of the R groups to be attached through an oxygen atom and only permits one residue to be present, whereas the formula at page 10 does not permit its R groups to be attached through an oxygen atom and permits up to six of the residues to be present. There is no original disclosure of the structure recited at claim 59, line 2, where $n=1, 4, 5$, or 6. This number of repeats is not disclosed at the places pointed to by Applicants for support. For example, the structure in Figure 25 only has $n=3$, and the structure at originally-filed claim 1 only has $n=1$. There is no original disclosure of the structure recited at claim 59 in which R is a nitrogen protecting group. This definition or wording is not disclosed at the places pointed to by Applicants for support. For example, the structure at originally-filed claim 1

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discloses an acetyl group and does not describe it in terms of function. There is no original disclosure of the carbohydrate domains named TF, 2,6-STF, 2,6-ST_n, 3,6-ST_n or of the carbohydrate domains having the structures recited at claim 72, page 19, lines 1-5, and at claims 81 and 83. There is no literal disclosure of these carbohydrate domains, including in the sections of the disclosure cited by Applicants. For example, while page 19, line 20, of the specification recites a 2,6-ST carbohydrate domain, this is presumably not the same domain as the currently claimed 2,6-STF. Page 29, lines 9-12, of the specification lists penta- and tetra-saccharide carbohydrate domains, but none use the subscripts j', k', or l' as they occur at claim 72, page 19, lines 1-2, and none have as many as the 9 saccharide residues permitted by the claimed structure. Page 23, lines 1-5, of the specification lists a carbohydrate domain similar to that at claim 72, page 19, lines 4-5, but does not use the subscripts j' and k' and does not comprise as many as the 8 saccharide residues permitted by the claimed structure.

6. Claims 88-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 88 and 90-92 are dependent upon canceled claim 1.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 59-89 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47, 51-58, 61-71, and 89-92 of copending Application No. 10/205,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '021 application anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 90-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 5, 8, 12-19, 22-32, and 53-58 of U.S. Patent No. 6,660,714. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '714 patent anticipate the instant claims.

10. Instant claims 59-100 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/079,312 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the claim limitations discussed in paragraph 5 above, and does not disclose the carbohydrate domains recited in instant claims 84 and 85. Because the instant application has two additional inventors in comparison to U.S. Patent No. 6,660,714, the latter is available as prior art against the instant claims under 35 U.S.C. 102(e). Because the instant application has three additional inventors in comparison to the WO Patent Application 98/46246, the latter is available as prior art against the instant claims under 35 U.S.C. 102(a).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

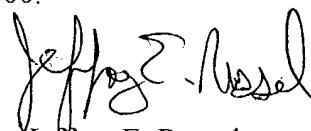
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 58-73, 77, 79-83, and 86-100 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 98/46246. The WO Patent Application '246 teaches the same glycoconjugates used for the same purposes recited in the instant claims. See, e.g., pages 17-21, 25, and 26, and Figures 20A and 20C.

13. Claims 58-73, 77, 79-83, and 86-100 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,660,714. See the above obviousness-type double patenting rejection. In addition, the specification and drawings also teach the compounds recited in the instant claims. See, e.g., Figures 20A and 20C.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
March 1, 2004